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Medical Research

The Program of the U. S. Public Health Service

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REMARKABLE CHANGES have taken place since World War II both in the substance of medical research in this country and in the sources of support for the total national medical research effort. Several penetrating analyses of the dynamic factors influencing these changes are readily available. It is not my purpose, however, to discuss the impact on present-day medical science of these complex factors such as the many-faceted wartime research and development program, and the rapidly converging interests of the physical, biological, and medical sciences. Rather, it is my purpose to consider briefly one significant alteration in the environment in which medical research is being conducted and to outline the role of the United States Public Health Service in encouraging and assisting medical research of high quality in universities, hospitals and other research institutions throughout the country.

Last year Dr. James A. Shannon, Director of the National Institutes of Health in Bethesda, Maryland, the research bureau of the Public Health Service, voiced the following opinion before the Clinical Sessions of the American Medical Association in Boston: "Viewed in perspective, the past decade has been the first period in our history when the na-

• Federal Government expenditures for medical research have increased apace in the last ten years. The increase in federal research funds has stimulated support from private sources; contributions from other than federal sources have doubled.

More than half of medical research funds are being used by universities, hospitals, and other nonprofit institutions, and less than one-fourth by laboratories of the Federal Government.

Grants-in-aid of research, fellowships and extended training are made on the advice of Advisory Councils made up of leaders in the various research fields. The previous record of research by staffs and faculties of institutions is taken into account. Special attention is given to unknown investigators and small projects.

Noninterference with a scientist in the conduct of research is a basic principle of all grants. He may change the direction of his research to pursue promising leads without asking permission.

Continuity of grants so that promising projects need not be abandoned at the end of a grant period is given special consideration.

tional medical research effort was financed on a scale reasonably commensurate with the potential humanitarian and economic gain to be derived from such effort."¹ In this discussion of "Trends in Medical Research," Dr. Shannon drew attention to a significant recent phenomenon—namely, widespread public interest and public determination to support medical research. Such vital encouragement of medi-

¹ Presented before the Section on Public Health at the 86th Annual Meeting of the California Medical Association, Los Angeles, April 28 to May 1, 1957.

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cal scientists has resulted both in the augmentation of total funds available from all private and public sources, and in increased appropriations of federal tax funds in support of medical research.

It is estimated that in 1947, the total national expenditure for medical research amounted to about \$87.5 million, more than twice the amount available for these purposes in the immediate pre-war period. Of the 1947 expenditures, federal tax support amounted to \$28 million, about 32 per cent of the total; in 1940, just before the war, the federal contribution to our national medical research program was about \$3 million, about 7 per cent of the total. The best available figures for 1957 at the time of this writing indicated that some \$330 million was to be spent for medical research, with roughly 56 per cent of that amount (\$186 million) to be supplied by the Federal Government. Thus, in the last 11 years, total national medical research funds have increased almost fourfold; federal contributions in support of medical research have increased more than sixfold during the same period, and now represent more than half of the total.

It is highly significant that, during this same post-war period, support of medical research from other sources—from industry, from private philanthropy and from income from endowment—has not fallen, as some had feared, but in fact has doubled. This increase, however, has not been proportional to that of the federal share. In this regard it is worthy of emphasis that federal expenditures for medical research have stimulated and encouraged more substantial support from other sources. It may also be pertinent to point out that despite this substantial growth, today less than 5 per cent of the nation's total research and development effort is devoted to medical research.

Of equal importance to the sources of financial support of medical research are the channels through which these funds are expended. Although more than half of the national medical research funds are derived from federal appropriations and only about one-sixth from private sources other than industry (philanthropy, plus income from endowment), almost the reverse is true in terms of use. More than half of medical research funds are being used by universities, hospitals and other nonprofit institutions and less than one-quarter by research laboratories of the Federal Government. Industry contributes about one-fourth of the total and expends almost an equal proportion. Stated in slightly different terms, of the \$255 million medical research program carried on in nonfederal laboratories and research institutions, \$111 million, or almost 45 per cent of the cost of all private medical research, is being met with federal funds.

Five federal agencies—the Department of Defense, the Atomic Energy Commission, the Veterans Administration, the National Science Foundation and the Department of Health, Education, and Welfare—are each making a significant contribution to the nation's medical research effort. The roles assigned to each through legislative authorization merge one with the other, but there can be little doubt that these programs are complementary and in no sense compete either for federal funds or in the application of their resources to useful purposes.

At present the Department of Health, Education, and Welfare, and particularly its component health agency, the Public Health Service, occupies a dominant place in the support of medical research through the use of federal tax funds. In turn, the National Institutes of Health, the principal research arm of the Public Health Service, is charged with dual medical research responsibilities. One of these responsibilities is to conduct medical and related research within its own laboratories and facilities, including the Clinical Center at Bethesda, Maryland, and a number of field stations in various parts of the country. The other is to aid in the support of individual scientists or groups of scientists working in universities, hospitals, laboratories, and other public and private nonprofit institutions throughout the country. It may be of interest to note that more than two-thirds of National Institute of Health (NIH) funds are expended in our so-called extramural activities—grants and awards to non-federal scientists. Less than one-third is spent on intramural or direct operations. Although the NIH constitutes the primary focus of medical research activity within the Public Health Service, the other principal Bureaus of the Service—the Bureau of Medical Services and the Bureau of State Services—are also engaged in investigative and research activities. It is a fundamental belief of those who guide Public Health Service programs that an active research program is essential to the establishment and maintenance of highest standards of performance in all its assigned tasks.

The roots of the Public Health Service program of medical research can be traced back readily to 1887, when the service established one of the first bacteriology laboratories in this country. This was in response to the urgent need to guard against the introduction and transmission of epidemic disease by the large number of persons then flocking to these shores. Those familiar with the history of modern preventive medicine will recognize such names as Rosenau, Goldberger, Anderson, Frost, Lumsden and others that were identified with the Public Health Service Hygienic Laboratory, which in 1930 became the National Institutes of Health.

In 1937 Congress established the first of our present-day categorical institutes, the National Cancer Institute. Six additional categorical institutes were created in the post-war period 1948-1950: National Heart Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Metabolic Diseases, National Institute of Dental Research, National Institute of Mental Health, and National Institute of Neurological Diseases and Blindness. The Division of Research Grants, with administrative responsibility for the management and policy direction of the Public Health Service research grant program, was also established in the same period.

Each institute has been authorized by Congress to conduct research within its own facilities. In addition, each is authorized to support research into the causes, diagnosis, prevention and treatment of diseases and disabilities of man through grants and fellowships to nonfederal scientists. The institutes also support certain types of academic and research training.

Congress, in establishing these institutes, provided a very broad interpretation of each categorical area so that scientists seeking support of their research activities need not fear restrictive limitations on the project design or the direction in which their investigative efforts might lead. To fill any gaps that might lie outside the interests of one or more institutes, Congress has authorized the Division of Research Grants to make grants of a totally non-categorical nature.

More recently, additional research grant and award authority has been assigned to the Public Health Service. Today, not only the National Institutes of Health, but also the Division of Hospital and Medical Facilities and the Division of Nursing Resources in the Bureau of Medical Services, the Division of Sanitary Engineering Services, and the Division of Special Health Services in the Bureau of State Services are actively engaged in the Public Health Service research program.

By Congressional authority, nine National Advisory Councils have been established as advisors to the Public Health Service. No research or training grant may be made by the Surgeon General unless recommended for approval by one of these councils. Seven of the councils advise the seven institutes of the National Institutes of Health on their respective programs, in addition to reviewing and recommending appropriate action on applications for grant support. The National Advisory Health Council reviews applications for general or non-categorical research grants not falling within the interest of the institutes, and advises the Surgeon General on matters relating to general health activities and functions of the service. The Federal

Hospital Council advises the Surgeon General on matters relating to the administration of the Hospital Survey and Constructions Program and reviews applications for grants-in-aid of projects relating to hospital services, facilities, and resources.

The National Advisory Council on Health Research Facilities, established in July 1956, reviews and recommends appropriate action on applications submitted by universities or other nonprofit institutions for assistance in the construction and/or equipping of additional facilities for the conduct of research in the sciences relating to health.

In view of the large number of applications submitted to the National Institutes of Health, covering the entire range of medical and biological research, the National Advisory Councils require the advice of many technical consultants. It was estimated that between 9,000 and 10,000 applications would be processed in 1957, of which some 6,000 would be supported through grants. The Division of Research Grants, therefore, has established over thirty study sections and other review committees. The members of these study sections and review committees are recognized leaders in the various fields of research, and, for the most part, are scientists in nonfederal agencies. In effect, then, these scientists, representing diverse fields and interests outside of government, act as technical advisors to the National Advisory Councils and to the Surgeon General. They accept responsibility not only for providing technical advice on applications for research support, but also, in conjunction with the councils, for surveying as scientific leaders the status of research in their particular fields in order to determine areas in which additional activity should be initiated or expanded.

Let me now outline briefly the principal types of grants and awards made by the Public Health Service in support of research, training, and construction:

1. *Research Grants.* Research grants are made to universities, hospitals, laboratories and other public or private institutions and to individuals for support of research projects in health, medicine and allied fields, including experiments or demonstrations relating to the development, utilization, and coordination of hospital services, facilities, and resources. The major objectives of the research grant program are (1) to expand medical and biological activities in research institutions throughout the country; (2) to provide on-the-job training for scientific personnel in connection with the research being conducted; and (3) to stimulate new investigations in fields needing exploration. These funds provide for salaries, equipment, supplies, travel and other expenses.

2. *Research Fellowships.* Research fellowships of five types are available: (a) *Predoctoral Research Fellowship*, awarded to qualified persons who hold a bachelor's degree or equivalent training. Fellows are expected to carry on studies oriented toward graduate training in fields related to the health sciences. (b) *Postdoctoral Research Fellowship*, awarded to qualified persons holding a doctor's degree in medicine, dentistry or related fields. Stipends and extra allowances are awarded under established Public Health Service policy. (c) *Special Research Fellowship*, awarded to qualified applicants who have demonstrated unusual competence for research, or who require specialized training for a specific problem. The amount of the stipend is set in each case. (d) *Student Part-time Research Fellowship*, designed to give students in medicine, dentistry, nursing and public health an opportunity to explore the research field in the hope that many of those supported will enter into full or part-time research careers. A predetermined number of these fellowships may be awarded each year. (e) *Senior Research Fellowship*, granted in support of preclinical science investigators between the completion of postdoctoral training and eligibility for permanent academic appointment. These funds provide for salaries plus research expenses not exceeding \$2,000. The Senior Research Fellows may also apply for research grants to support their research.

3. *Undergraduate Training Grants.* Undergraduate training grants are awarded to medical schools, dental schools, public health schools and schools of nursing to assist in developing expanded and better integrated undergraduate instruction in the special fields concerned. It is the responsibility of the institution to determine the most appropriate use of the funds.

4. *Graduate Training Grants.* Graduate training grants are awarded to public and private nonprofit institutions interested in providing special training for researchers, teachers and prospective practitioners interested in public service. These funds may be used to improve facilities and to provide salaries for faculty, staff and trainees, along with necessary supplies and materials.

5. *Traineeships.* A series of traineeship stipends are awarded either directly to the individual in training or through a training grant to the institution for this purpose. Traineeships are awarded to physicians and other professional personnel in order to encourage specialization in one of the branches of medicine supported. Stipends and extra allowances are made under established PHS policy.

6. *Health Research Facilities.* Under the Health Research Facilities Act, July 1956, the Congress

authorized the establishment of a program to assist in the construction and/or equipping of additional facilities for the conduct of research in the sciences relating to health by providing grants-in-aid on a matching basis to public and private nonprofit institutions. The amount of federal funds awarded may not exceed 50 per cent of the total costs of the research portion of the facility, the remaining sum to be provided from nonfederal sources.

Public Health Service programs in support of research and training in universities, hospitals and other nonfederal institutions have justified continued Congressional interest, as evidenced in the following table which shows the growth of the programs by appropriation year:

	Research Grants	Fellowships	Training Grants*	Health Research Facilities
1946.....	\$ 780,000	\$ 44,000	\$ 29,000	\$
1947.....	3,576,000	178,000	250,000
1948.....	9,145,000	520,000	2,810,000	2,303,000
1949.....	10,871,000	1,115,000	3,930,000
1950.....	13,065,000	1,448,000	6,415,000	5,775,000
1951.....	16,713,000	1,565,000	6,928,000	9,459,000
1952.....	18,173,000	1,755,000	7,392,000	4,625,000
1953.....	20,374,000	2,024,000	8,194,000
1954.....	28,866,000	2,133,000	10,813,000
1955.....	33,918,000	2,562,000	11,051,000
1956.....	38,038,000	2,800,000	14,502,000
1957.....	93,300,000	5,397,000	28,075,000	30,000,000

* Includes traineeships.

May 8, 1957

Many other aspects of the Public Health Service research grant and award program could profitably be reviewed. Within the limitations of this presentation, however, it is necessary to select only a few additional principles that are basic to the operation of our total program. I shall refer to the need for safeguarding the scientific freedom of the investigator; the importance of continuity and stability of support; and to equitable distribution, geographic and otherwise, of research grants and awards.

Scientific Freedom of Investigator

Noninterference with the scientist in the conduct of his research is the most important principle underlying our program. A number of safeguards have been established to insure that the Public Health Service in no way controls the research carried out under the grants. These measures include: (1) The legislation itself, which vests in the National Advisory Councils the authority for selecting the applications meriting support; (2) the awarding of grants on the basis of competent review by the applicant's scientific peers; (3) permission to publish results without previous clearance from or notification to the Public Health Service; (4) freedom of the grantee, once a grant has been awarded, to make substantial transfers between budget categories without previous approval; (5) provision for the grantee institution to administer the grant under

the rules and regulations of that institution, rather than under Public Health Service rules; (6) vesting in the grantee institution of title to all equipment purchased with grant funds; and (7) authority to the scientist to change his research plans without need for getting approval if he finds new and more promising leads. These safeguards guarantee to the scientist that he will have the scientific freedom required for the best work.

Stability of Support

Stability of support for the investigator is also one of the chief concerns of those responsible for administering the research program of the Public Health Service. Readily conceding the preferability of endowment or other so-called "hard money," but recognizing the often frustrating and disappointing results of universities in obtaining such funds, the Public Health Service has developed policy to provide the maximum stability practicable under an annual appropriation project plan. An applicant who receives a grant for a year may also receive a moral commitment of from one to four additional years of support—a promise to pay, provided Congress appropriates the necessary funds. At the end of the committed period, the grantee often receives additional years of support after the National Advisory Councils and study sections have evaluated his needs and plans. Under this procedure a grantee may conceivably receive Public Health Service support of his research for an indefinite period.

Distribution of Research Grants and Awards

On several occasions studies have been made of the distribution of Public Health Service grant

awards to institutions and to geographic areas of the country. As might be expected, the number of institutions sponsoring scientists receiving Public Health Service awards is quite large and increases with each passing year. It is of interest, however, that a relatively small number of institutions account for a large number of grants. For example, ten institutions received 35 per cent of all Public Health Service research grants in 1953. Using an index of research potential based on the percentage of faculty members listed in American Men of Science and the percentage of articles they have published in 53 leading periodicals, one finds a rather pronounced degree of correlation between grant awards and the research potential of an educational institution. The same is true when grants are analyzed geographically. Last year, for instance, the Pacific States (California, Oregon and Washington) received 12.8 per cent of the grants, whereas 11.7 of established scientists were located in this area. Since projects are evaluated primarily on the basis of merit, these findings were anticipated even though effort is made to help unknown investigators and institutions or agencies that have only small research programs. We believe these efforts are most important in the individual case even though they affect only slightly the over-all distribution of funds.

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